

REMARKS

Applicant respectfully requests entry of the amendments and remarks submitted herein. Claim 1 has been amended; claims 10, 11, and 15-66 have been canceled; and new claims 67-77 have been added. Accordingly, claims 1-9, 12-14, and 67-77 are pending.

As a preliminary note, support for the amendments to claim 1 and for new claims 67-77 can be found in the specification as shown in the following table, *inter alia*.

Claim	Support in Specification
1	Page 9, lines 10-25
67	Page 9, lines 13-16
68	Page 9, lines 16-19
69	Page 9, lines 22-23
70	Page 10, lines 5-8
71	Page 10, lines 5-8
72	Page 10, lines 5-8
73	Page 9, lines 25-26
74	Page 9, line 30
75	Page 10, line 1
76	Page 10, line 2
77	Original claim 24

35 U.S.C. § 112

Claims 1-7, and 9-15 were rejected under 35 U.S.C. 112, first paragraph. To the extent that this rejection might be maintained with respect to the amended claims, it is respectfully traversed.

Amended claim 1 is directed to a therapeutic device for neural tissue regeneration comprising a tube, or a polymeric sheet that is rolled into a tube, which comprises a biodegradable polymer that biodegrades to provide sustained release of an anti-inflammatory compound to the neural tissue. From the bottom of page 8 to the middle of page 10, the specification provides a general discussion of how the claimed devices can be prepared. From

the middle of page 10 to the bottom of page 12, the specification provides guidance regarding anti-inflammatory agents that can be incorporated into the devices of the invention and how they can be incorporated into the devices of the invention. From the bottom of page 12 to the top of page 24, the specification provides an extensive discussion regarding how to prepare the biodegradable polymers recited in the claims. From page 35 to page 38 the specification describes how to spatially direct cellular growth with the claimed devices. At Example 1 (pages 39-44) the specification provides details for preparing representative biodegradable polymers of the invention. Finally, at Figure 1, a bioactive tubular device of the invention is illustrated.

In addition to the extensive guidance provided by the specification, it is noted that the relative skill of one working in the field is high; typically one working in the field possesses a graduate degree and often some post-doctoral training. Additionally, amended claim 1 recites device for neural tissue regeneration comprising a tube or a polymeric sheet that is rolled into a tube. This claim is not unduly broad.

It is respectfully submitted that one skilled in the art could readily prepare the claimed devices without undue experimentation given the breadth of the claims, the teaching provided by the specification, and the high level of skill in the field. Accordingly, it is submitted that the amended claims meet the requirements of 35 U.S.C. §112, first paragraph; withdrawal of the rejection is appropriate and is requested.

35 U.S.C. §102

Claims 1-7 and 9-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Erdmann et al. This rejection is respectfully traversed.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Independent claim 1 is directed to a therapeutic device for neural tissue regeneration comprising a tube, or a polymeric sheet that is rolled into a tube, which comprises a

biodegradable polymer that biodegrades to provide sustained release of an anti-inflammatory compound to the neural tissue.

Erdmann et al. discusses polymeric prodrugs that include salicylic acid in the polymer backbone. The prodrugs "may have potential in a variety of applications (i.e. inflammatory bowel disease)." See Erdmann et al. at the Abstract. At page 1946, Erdmann et al. conclude, "Because salicylic acid is released upon hydrolysis, this polymeric prodrug may show potential for a variety of applications ranging from the treatment of inflammatory bowel disease to periodontal prosthetics. Given the pH dependent degradation we believe these polymers will be significant in treating gastrointestinal disease where it is important to release the salicylic acid derivative at the desired site - the lower intestine (basic conditions) - rather than stomach (acidic conditions). There is no discussion of medical devices, and no discussion of neuronal applications in Erdmann et al.

Erdmann et al. does not disclose all the elements of claim 1. Claim 1 recites "a tube, or a polymeric sheet that is rolled into a tube." There is no discussion in Erdmann et al of a device that comprises these structural elements. Accordingly, Erdmann et al. does not disclose each element of independent claim 1. Thus, Erdmann et al. does not anticipate the instant claims. Withdrawal of the rejection is appropriate and is respectfully requested. It is further noted that new dependent claims 67-76 include additional structural elements that are not described by Erdmann et al.

35 U.S.C. §103

Claims 1-7, 9-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Erdmann et al. This rejection is respectfully traversed.

Claim 1 and the content of Erdmann et al. are discussed above.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. §2142. The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Rejections on obviousness cannot be sustained with mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. M.P.E.P. §2142.

It is respectfully submitted that the Examiner has not established that the instant claims are *prima facie* obvious over Erdmann et al. taken alone. Applicant has discovered devices that

can direct the growth, enhance the regeneration and promote the healing of neural tissue (please see the specification at page 1, lines 8-9). The single document Erdmann et al. does not include any discussion of medical devices or neuronal applications for the polymers discussed therein. Instead, Erdman et al. suggests that the polymers discussed therein might be useful as prodrugs for treating gastrointestinal diseases. As discussed above in the remarks relating to the rejection under 35 U.S.C. §102, amended claim 1 recites structural elements that are not suggested anywhere in Erdmann et al. (e.g. a tube, or a polymeric sheet that is rolled into a tube). Additionally, Erdmann et al. does not suggest that the polymers discussed therein will have any effect on the growth, regeneration, or healing of neural tissue. Accordingly, one skilled in the art would not have found any motivation in Erdmann et al. to prepare the instantly claimed devices, which are structured to facilitate the growth, regeneration, or healing of neural tissue. Finally, Erdmann et al. does not provides any guidance regarding how to prepare or structure the instantly claimed devices. In light of these facts, it is respectfully submitted that the instant claims are not *prima facie* obvious over Erdmann et al. taken alone. Accordingly, withdrawal of the rejection under 35 U.S.C. §103 is appropriate and is respectfully requested.

At page 6 of the Office action, the Examiner states "it would have been obvious to one of ordinary skill in the art that the polymer could be used in other conventional ways in which biodegradable polymers are known." This conclusory statement is the only evidence provided by the Examiner to demonstrate that the instantly claimed devices would have been obvious in light of Erdmann et al. It is respectfully submitted that this statement does not represent a clear articulation of the reason(s) why the claimed devices would have been obvious. This is especially true since Erdmann et al. does not include any discussion of devices; any discussion that the polymers therein have beneficial properties relating to neural growth, regeneration, or healing; any suggestion of the recited structural elements of the claimed devices; or any suggestion of how to prepare the claimed devices. Accordingly, the Examiner has not met the burden to establish a *prima facie* case of obviousness over Erdmann et al. If the Examiner maintains the rejection with respect to the amended claims, Applicant requests that the Examiner clearly articulate reasons that demonstrate that the claimed devices would have been obvious over the prodrug polymers discussed in Erdmann et al.

New Claim 77

New claim 77 is directed to a device that comprises a pattern of biologically active molecules on the biodegradable polymer. In the response filed 13 May 2008, Applicant elected a device without such biologically active molecules present. Accordingly, new claim 77 does not read on the previously elected species of the invention. If the instant claim 1 is found to be patentable, Applicant respectfully requests that the Examiner examine and find dependent claim 77 to also be patentable. It is respectfully submitted that examination of dependent claim 77 will not require additional searching once independent claim 1 has been found to be patentable.

Co-assigned Related Cases

To supplement the list provided on 31 January 2005, Applicant would like to bring the following co-assigned patents and applications that relate to subject matter that is similar to the subject matter of the instant application to the Examiner's attention.

Serial or Patent Number	Attorney Docket Number
7,122,615	01435.008US1
11/516,464	01435.008US2
6,602,915	01435.010US1
6,486,214	01435.012US1
10/924,238	01435.012US3
11/524,664	01435.013US4
6,468,519	01435.014US1
6,685,516	01435.016US1
6,689,350	01435.017US1
11/956,189	01435.017US3
11/956,202	01435.017US4
6,613,807	01435.021US1
11/732,653	01435.021US3
7,411,031	01435.023US1
12/026,925	01435.023US2
7,396,527	01435.025US1

10/949,955	01435.031US2
11/435,812	01435.039US1
11,915,284	01435.040US1
12/303,682	01435.042US1
10/503,838	01435.060US1
10/504,121	01435.061US1
10/716,577	01435.062US1
10/532,703	01435.063US1
10/861,881	01435.064US1

CONCLUSION

In light of the above amendments and remarks, claims 1-9, 12-14, and 67-77 are believed patentable. The Examiner is invited to contact Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3503. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account 50-3503.

Respectfully submitted,

Kathryn E. Uhrich et al.

By their Representatives,

Viksnins Harris & Padys PLLP

Customer Number 53137

PO Box 111098

St. Paul, MN 55111-1098

(952) 876-4092

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By: 

Robert J. Harris

Reg. No. 37,346